

CHAPTER 43-15.1 WHOLESALE DRUG DISTRIBUTORS

43-15.1-01. Definitions. As used in this chapter:

1. "Board" means the state board of pharmacy.
2. "Manufacturer" means any person engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.
3. "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including a wholesale drug distributor, engaged in the delivery or distribution of prescription drugs and involved in the actual, constructive, or attempted transfer of a drug in this state to other than the ultimate consumer, where the financial value of the drugs is equivalent to at least five percent of the total gross sales of the pharmacy distributor.
4. "Prescription drug" means any drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal Food, Drug and Cosmetic Act.
5. "Wholesale drug distribution" means sale of prescription drugs to persons other than a consumer or patient. The term does not include:
 - a. Intracompany sale, which is a sale between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity.
 - b. The purchase or other acquisition by a hospital pharmacy or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospital pharmacies or health care entities that are members of such organizations.
 - c. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
 - d. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, among hospital pharmacies or other health care entities that are under common control.
 - e. The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, for emergency medical reasons.
 - f. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
 - g. A transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.
 - h. A manufacturer or a manufacturer's sales representative or agent.
6. "Wholesale drug distributor" means any person engaged in the wholesale drug distribution, including manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain

drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; sales agents; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospital pharmacies; nursing home pharmacies or their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term does not include any common carrier or individual hired solely to transport prescription drugs.

43-15.1-02. Prohibited drug purchase or receipt - Penalty. No person may knowingly purchase or receive any prescription drug from any source other than a wholesale drug distributor, manufacturer, pharmacy distributor, pharmacy, or other person licensed pursuant to the laws of this state except where otherwise provided. A person violating this section is guilty of a class A misdemeanor. A second violation is a class C felony.

43-15.1-03. Wholesale drug distributor advisory committee. The board shall appoint a wholesale drug distributor advisory committee composed of three members. One member must be a representative of a pharmacy and may be a pharmacy distributor, but may not be an employee of the board. One member must be a representative of wholesale drug distributors. One member must be a representative of drug manufacturers. In making appointments, the board shall consider recommendations received from wholesale drug distributors, pharmacy distributors, and drug manufacturers and shall adopt rules that provide for solicitation of such recommendations. The advisory committee shall review and make recommendations to the board on the merit of rules of the board which deal with wholesale drug distributors, pharmacy distributors, and drug manufacturers. The board may not adopt any rule affecting wholesale drug distributors or pharmacy distributors without first submitting the proposed rule to the committee for review and comment.

43-15.1-04. Wholesale drug distributor and pharmacy distributor licensing requirements - Penalty.

1. No person may act as a wholesale drug distributor or pharmacy distributor without first obtaining an annual license to do so from the board and paying the annual fee required by the board.
2. The board may grant a temporary license when the wholesale drug distributor or pharmacy distributor first applies for a license to operate within this state. A temporary license is valid until the board finds that the applicant meets the requirements for regular licensure.
3. The licensee shall operate in a manner prescribed by law and according to the rules adopted by the board.
4. The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state if operations are conducted at more than one location and there exists joint ownership and control among all the entities.
5. An applicant for a license and a licensee shall satisfy the board that the applicant or licensee has and will continuously maintain:
 - a. Adequate storage conditions and facilities;
 - b. Minimum liability and other insurance as may be required under any applicable federal or state law;
 - c. A viable security system that includes after hours, central alarm, or comparable entry detection capability; restricted premises access; comprehensive

employment applicant screening; and safeguards against all forms of employee theft;

- d. A system of records that describes all wholesale drug distributor and pharmacy distributor activities for at least the most recent two-year period and which is reasonably accessible in any inspection authorized by the board;
- e. Principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;
- f. Complete, updated information, to be provided the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed under this chapter, including pertinent licensee corporate, if applicable, or other ownership, principal, key personnel, and facilities information;
- g. Written policies and procedures that assure reasonable wholesale drug distributor and pharmacy distributor preparation for, protection against, and handling of any facility security or operation problems, including problems caused by natural disaster or government emergency; inventory inaccuracies or product shipping and receiving; outdated product or other unauthorized product control; appropriate disposition of returned goods; and product recalls;
- h. Sufficient inspection procedures for all incoming and outgoing product shipments; and
- i. Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

All requirements by the board under this subsection must conform to wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. In case of conflict between any wholesale drug distributor licensing requirement imposed by the board under this subsection and any wholesale drug distributor licensing guideline of the food and drug administration, the guideline controls.

- 6. An agent or employee of any licensed wholesale drug distributor or pharmacy distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.
- 7. A person who violates this section is guilty of a class C felony.

43-15.1-05. Out-of-state wholesale drug distributor and pharmacy distributor licensing requirements - Penalty.

- 1. An out-of-state wholesale drug distributor or pharmacy distributor or a principal or agent of the distributor may not conduct any business in this state unless the distributor has obtained a license to do so from the board and paid the fee required by the board.
- 2. Application for a license under this section must be made on a form furnished by the board.
- 3. The issuance of a license under this section does not change or affect tax liability imposed by this state on any out-of-state wholesale drug distributor or pharmacy distributor.

4. The board, by rule, may license out-of-state wholesale drug distributors or pharmacy distributors on the basis of reciprocity to the extent that an out-of-state wholesale drug distributor or pharmacy distributor:
 - a. Possesses a valid license granted by another state pursuant to legal standards comparable to those of this state which must be met for obtaining a license under the laws of this state; and
 - b. Shows that the other state would extend reciprocal treatment under its own laws to a wholesale drug distributor or pharmacy distributor of this state.
5. A person who violates this section is guilty of a class C felony.

43-15.1-06. License renewal procedures. The board shall mail an application for license renewal to each licensee before the first day of the month in which the license expires. If application for renewal of the license, along with required fee, is not received by the board before the first day of the following month, the license expires on the last day of that month.

43-15.1-07. Adoption of rules. Every rule adopted by the board with respect to implementation of this chapter must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. In case of conflict between a rule adopted by the board and a guideline of the food and drug administration, the guideline controls.

43-15.1-08. Violations of chapter - Effect on licensure. If the board determines that a wholesale drug distributor or wholesale pharmacy distributor has committed an act or is engaging in a course of conduct which constitutes a clear and present danger to the public health and safety in this state, the board may restrict or suspend the wholesale drug distributor's or pharmacy distributor's license. The board has the burden of proving that a wholesale drug distributor or wholesale pharmacy distributor is a clear and present danger to the public health and safety.

43-15.1-09. Inspection powers and access to wholesale drug distributor records - Penalty. The board or a designee of the board may conduct inspections during normal business hours upon all open premises purporting or appearing to be used by a wholesale drug distributor or wholesale pharmacy distributor in this state. A distributor who provides adequate documentation of the most recent satisfactory inspection less than three years old by either the United States food and drug administration or a state agency determined to be comparable by the board is exempt from further inspection for a period of time determined by the board. This exemption does not bar the board from initiating an investigation pursuant to a complaint regarding a wholesale drug distributor or pharmacy distributor. A wholesale drug distributor may keep records at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped; provided, that the records are made available for inspection within three business days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drugs recordkeeping. A person who fails to provide a duly authorized person the right of entry as provided in this section is guilty of a class A misdemeanor for the first conviction and a class C felony for each subsequent conviction.

43-15.1-10. Judicial enforcement. Upon proper application by the board, a court of competent jurisdiction may grant an injunction, restraining order, or other order as may be appropriate to enjoin a person from offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit, or license is required by any applicable state law, including this chapter, upon a showing that the acts or practices were or are likely to be performed or offered to be performed without a certificate of registration or authority, permit, or license. An action authorized under this section is in addition to and not in lieu of any other penalty provided by law and may be brought concurrently with other actions to enforce this chapter.